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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,590	12/13/2007	Ian Revie	DEP5303USPCT	7442

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EXAMINER

KISH, JAMES M

ART UNIT	PAPER NUMBER
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3737

NOTIFICATION DATE	DELIVERY MODE
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04/09/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/598,590	Applicant(s) REVIE ET AL.	
	Examiner JAMES KISH	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 45,46,49-51,54-60,62-64,77 and 79-81 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 45,46,49-51,54-60,62-64,77 and 79-81 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/28/12</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

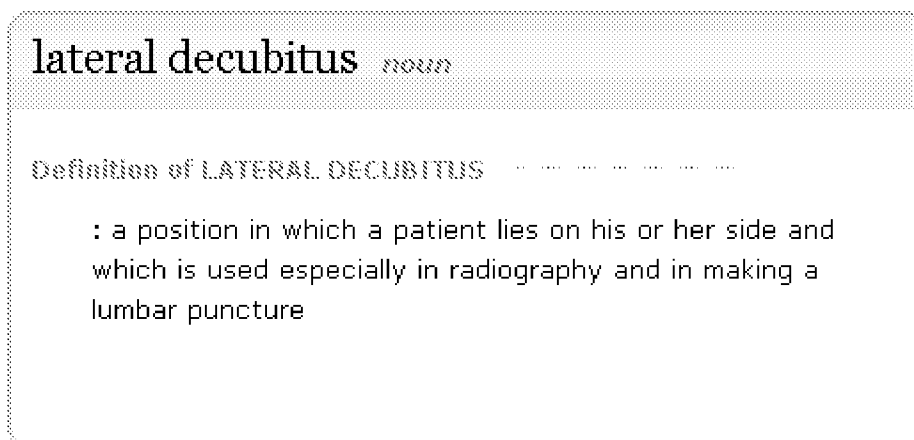
Response to Arguments

Applicant's arguments filed March 28, 2012 have been fully considered but they are not persuasive.

Firstly, the objections to the specification, the drawings and the claims have been overcome by the amendments to the application.

Secondly, the 35 USC 101 rejection of claim 82 is no longer applicable due to claim 82 being cancelled. The 35 USC 101 rejections of claims 45 and 77 have not been overcome because a data processing device is not considered a particular machine because any general purpose computer is a processing device.

The Applicant argues that the prior art fails to disclose the claimed method of registering the pelvis of a patient in a lateral decubitus position. The Examiner respectfully disagrees. Merriam-Webster's Online Dictionary defines lateral decubitus as follows:



As highlighted by the Applicant, Kienzle discloses "the patient is placed on his or her side on the operating room table and draped in the usual fashion,' and thereafter the

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surgeon uses a probe to identify landmarks.” As such, Kienzle positively teaches the claimed method of registering the pelvis of a patient in a lateral decubitus position.

Regarding the Applicant’s arguments that it would not be possible to determine the left ASIS and right ASIS via the methods of Kienzle (which the Examiner does not acquiesce to such arguments since Kienzle positively teaches the registration of these landmarks while the patient lays in a lateral decubitus position), it is noted that Kienzle teaches that “other bony landmarks may be selected without departing from the instant invention (end of paragraph 45).” Therefore, it would be entirely possible and obvious to one of ordinary skill in the art to determine these or any other significant bony landmarks via the methods of Kienzle in order to register the pelvis.

At the bottom of page 10, the Applicant states that “neither Kienzle nor Sarin disclose determining (or calculating) the frontal and mid-sagittal planes, and then using those planes to determine (or calculate) a third plane that is orthogonal to the frontal and mid-sagittal planes.” This is followed by the Applicant’s re-iteration of paragraph 46 of Kienzle in which it clearly states that the three planes that are determined are the frontal plane, the axial plane and a sagittal plane. Therefore, this argument is not persuasive. And furthermore, Kienzle states that “Alternatively, other axes and planes may be defined without departing from the instant invention (end of paragraph 46).” Therefore, it would be found obvious to determine these even if Kienzle failed to explicitly teach these planes.

For these reasons, the rejections of the claims is maintained and repeated below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45 and 77 are rejected under 35 USC 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing *en banc* pending). The claims relate to determining cardinal planes (or planes parallel to the cardinal planes) of a subject's pelvis. The independent method claims do not comprise a sufficient tie to a particular machine and it is noted that a data processing device is not considered a particular machine as any general purpose computer is a processing device. Furthermore, there is no transformation of underlying subject matter to a different state or thing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-46, 49-51, 54-60, 62-64, 77 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III (US Patent Pub. No. 2002/0077540) – herein referred to as Kienzle – in view of Sarin et al. (US Patent No. 6,711,431) – herein referred to as Sarin.

Kienzle discloses a computer assisted surgery system for assisting a surgeon in orthopaedic procedures. Kienzle discloses that “the patient is placed on his or her side on the operating room table and draped in the usual fashion,” and thereafter the surgeon uses a probe to identify landmarks. Therefore, Kienzle teaches the lateral decubitus position. As described in the Abstract, “the surgeon is provided with information regarding the orientation of the cup with respect to a pelvic reference frame that is based on accepted pelvic landmarks. The positions of each landmark is calculated by the system when a probe with a virtual tip, separate from its physical tip, is

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overlaid on the landmark in roughly orthogonal images of the pelvis." In paragraph 46, Kienzle states that the "frontal" plane, the axial plane and a third, sagittal plane are defined (see Figure 9: third plane not shown). As can be seen in Figure 9, these planes are parallel to the cardinal planes of the pelvis and at least the landmarks 182 and 183 (note: there is a third landmark 184) are illustrated as being common to both planes 188 and 189. Kienzle does teach that "one or more landmarks or points" may be defined by the probe (see paragraph 44). Furthermore, Kienzle comprises computer that is used with its computer assisted surgery system, comprising a data processing device and a memory for storing instructions and data required to perform the methods as previously taught. However, Kienzle never states that more than three landmarks are used.

Sarin teaches non-imaging, computer assisted navigation systems for hip replacement surgery. In column 8, Sarin teaches that "in pelvic definition step 148, the physician uses an optically trackable manual probe 50 to palpate at least three, and preferably four, easily located anatomical landmarks on the pelvis (see lines 8-11)." It would have been obvious to one of ordinary skill in the art at the time the invention was made that using four points, as taught by Sarin, would better define the pelvic plane (see column 8, lines 26-28).

Regarding claim 46, it can be seen in Figure 9 that at least the landmarks 182 and 183 (note: there is a third landmark 184) are illustrated as being common to both planes 188 and 189.

Regarding claim 49, Kienzle states that the planes are the frontal, the sagittal and the axial (or transverse) planes.

Regarding claims 50 and 51, Kienzle teaches that “Alternatively, the virtual probe representation can be replaced with a straight line, a curved line, a plane, a curved surface, or some other graphic that allows for the alignment of the virtual probe with one or more landmarks or points (*see* paragraph 44).” Therefore, Kienzle does not limit its device to only three points and could provide any number of landmarks. Furthermore, Kienzle teaches, “Alternatively, other axes and planes may be defined without departing from the instant invention (*see* paragraph 46).”

Regarding claim 54, as stated by the Abstract, “The positions of each landmark is calculated by the system when a probe with a virtual tip, separate from its physical tip, is overlaid on the landmark in roughly orthogonal images of the pelvis.”

Regarding claim 55, Kienzle utilizes images of the pelvis, as exemplified at least by paragraph 47 as stating, “As the surgeon moves the positioning instrument (191), the display is updated in real time to show, graphically, the pose of instrument and implant representation (195) relative to the images of the pelvis.”

Regarding claim 56, Sarin teaches a trackable marker attachable to the pelvis for tracking the position and orientation of the pelvis (*see* Figure 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a tracking marker as disclosed by Sarin in order to track in real-time the position of the pelvis in case the patient moves.

Regarding claim 57, Kienzle teaches applying a “virtual end” of a probe to respective anatomical features of the pelvis (*see* the Abstract).

Regarding claim 58, Kienzle teaches subcutaneously applying the "virtual end" of the instrument (*see* Figure 7).

Regarding claim 59, Kienzle teaches percutaneously applying the "virtual end" of the instrument (*see* Figure 7). Furthermore, Sarin teaches placing the physical end of its probe in percutaneous contact overlying an anatomical landmark (*see* column 8, lines 11-14).

Regarding claim 60, Sarin teaches that "the physician uses an optically trackable manual probe to palpate at least three, and preferably four, easily located anatomical landmarks on the pelvis.

Regarding claim 62, Kienzle shows in Figure 9 that landmarks 182 and 183 are located at the spina iliaca anterior superior, while landmark 184 is located at the symphysis pubis (*see* paragraph 46).

Regarding claims 63, Kienzle teaches, "Alternatively, other axes and planes may be defined without departing from the instant invention (*see* paragraph 46)." It would be obvious to one of ordinary skill in the art to utilize any landmarks that are known to reside within the desired plane when defining that plane with the system registration steps taught by Kienzle - "a person of ordinary skill is also a person of ordinary creativity, not an automaton. (KSR International Co. v. Teleflex Inc. et al.).

Regarding claim 64, the symphysis pubis is common to at least two of the planes shown in Figure 9, thereby being interpreted as the first and second planes.

Regarding claim 77, the combination of the prior art was previously described with regard to claim 45 in such a manner that it reads similarly on the limitations of claim 77. See the main body of the rejection.

Regarding claim 79, Kienzle states that the planes are the frontal, the sagittal and the axial (or transverse) planes.

Regarding claims 80 and 81, Kienzle teaches that both planes utilize the point at the pubic symphysis.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James Kish/
Primary Examiner, Art Unit 3737